Longitudinal Surveillance of HIV Treatment under the Emergency Plan (LSTEP)

The findings and conclusions in this presentation are those of the author and do not necessarily represent the views of The Centers for Disease Control and Prevention/the Agency for Toxic Substances and Disease Registry

Information is key to improving quality of care and treatment

- Measuring and improving quality of HIV care/ treatment programs:
  - M&E: group cohort results from national patient monitoring systems (if available)
  - Surveillance: individual-level cohort results from selected treatment sites
- Ideal (surveillance>M&E): obtain best/most feasible representative sample of individual-level cohort information across treatment facilities

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What we know

- Most national governments obtain and use aggregate, or “process,” data about their HIV treatment programs.
- For example:
  - # of facilities
  - # of individuals served
  - # of people trained

What we don't know

- Systemic constraints prevent easy access to HIV treatment programs information (outcomes/impact), such as proportion of HIV-infected patients:
  - Alive on ART at 6, 12, & 24 mo
  - On original first-line regimen at 6 & 12 mo
  - With improved functional status at 6, 12, and 24 mo
  - With undetectable viral load at 6 & 12 mo
  - Changes (rise) in CD4 at 6 & 12 mo

The (original) idea

- Develop a representative longitudinal database of persons on ART in national programs, in multiple countries
  - Abstract a minimum basic data set of process/ outcome information from patient medical records at a sample of medical facilities
  - Supplement record review with patient interviews
- Evaluate outcomes of HIV care/treatment programs
- Feedback to improve quality of HIV care/treatment
- Not a new idea: informed by US studies of people in HIV care (ASD, PSD, SHAS, SHDC, SHDC+, MMP)

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Objectives of LSTEP

- Measure selected indicators of HIV care/treatment process and outcome
- Analyze processes and outcomes by individual and facility (and national) variations
- Provide tool for the improvement of HIV care/treatment programs

The approach

- Draft proposal
- Catalyze some central PEPFAR funding
- Develop protocol and instruments
- Present to country teams for input and consideration in Country Operation Plans (COP)
- Support adaptation, planning, implementation among interested countries
- Seek USG multi-agency consensus for the project

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Collaborators and advisors

- CDC/GAP Care and Treatment Branch (Care and Treatment Team)
- CDC/GAP Epi and Strategic Info Branch (Surveillance, Informatics, Stats Advisor)
- CDC/GAP – OD
- CDC/DHAP
- USG country teams – CDC/GAP and USAID
- Ministries of Health – NACPs
- Implementing Partners (E.g. Columbia, Johns Hopkins)
- HRSA, USAID, OGAC, NIH, DOD

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Proposed outcomes measures (adult)

- Point of entry into HIV care, and source of referral to ART
- Time from eligibility to entry into ART program
- Retention in ART program
- Timing and duration of event:
  - —ART interruption or stop; transfer; death
  - —ART change (i.e., 1st to 2nd line)
- Adherence to ARV drugs

Proposed outcomes measures (adult)

- Change in health status
  - —Frequency of OI's, weight, functional status
- Prevalence/incidence of TB disease
- Incidence/duration of hospitalization
- Receipt of basic HIV care services (CPT)
- Sexual and alcohol/drug risk behaviors
- HIV drug resistance (special topic; limited sites)

Proposed Methods

- Data abstraction - sample of persons on ART
- Patient interview - subsample of persons on ART
- Specimen collection - small subset in selected sites
  - Monitor HIV drug resistance--separate protocol (under development)
- National ART program survey
- Facility survey (baseline with updates)

Proposed Methods

Retrospective cohort (existing patients)

- Immediately available data
- Describes "current" patient population
- Patients starting ART 6 and 12 mo before
- Data abstraction from patient records of last 6 and 12 mo
- Follow cohort prospectively at 6 mo intervals

Proposed Methods

Prospective cohort (new patients)

- Build prospective cohort--patients newly
- initiating ART
- Abstract data at baseline and every 6 months
- Linked baseline patient interview
- Linked follow-up interviews at 12 months (for consideration)

Pediatric LSTEP

- Pediatric concept paper developed
- Separate protocol for pediatrics
  - Run in (lagged) parallel with adult
- Attention to pediatric-specific issues in:
  - Objectives
  - Data elements
  - Sampling
  - Human subjects considerations

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Opportunities

- Review and improve data systems in facilities and countries (infrastructure support and development)
- Discover and investigate additional questions for targeted evaluation
- Complement related activities
  - USG targeted evaluation projects: ART lab monitoring, ARV adherence, and ARV costing
  - International HIV database projects: ART-LINC and IeDEA
  - HIV drug resistance monitoring of ART patients

Status of initiative

- Draft protocol refined at USG HQ multi-agency meeting (Jul, 05)
- Idea presented to countries for consideration (Aug, 05)
- Interested countries requested funding through FY06 COP (Sep-Oct, 05)
- Revised protocol disseminated (Oct, 05)
- Some instruments drafted and shared (Oct-Nov, 05)
- Provide support to interested countries (ongoing)
- Evolving process (ongoing)

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Country Adaptation

- Strive for standardization of some core data elements for multi-country comparisons
- Country adaptation is necessary and encouraged

Evolution of LSTEP

LSTEP concept has evolved as:

- Countries voiced their needs
- Appropriateness of outcomes for countries assessed
- Minimum common data set in countries audited
- Feasibility and need for patient interview considered
- Sampling considerations addressed (national, subnational, facility, individual)
- Ability to follow patients over time audited
- Human subjects review environment has shifted

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LSTEP adaptation to country-specific settings

Considerations:

- How is the national treatment program organized?
- What are the information needs of that program?
- What information is collected by the program?
- Is there a national patient monitoring system?
- Are national evaluation activities planned or underway?
- How to move national HIV care/treatment program evaluation agenda forward
  - near-term, medium-term, long-term

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How does HIVQUAL Differ from LSTEP

	HIVQUAL	LSTEP
Focus	Quality improvement	Surveillance
Method	Consultation, performance measurement, QI	Longitudinal cohort analysis
Target population	Adults	Adults & children
Indicators	HIV monitoring; adherence; ART; cotrimoxazole use; TB screening; health status	Retention; adherence; health status (e.g., wt, TB co-infection); basic care package; drug resistance
Data collection	Record abstraction	Record abstraction & interview
Cost/staffing	$150 – 300,000 Project coordinator; data manager	$200 – 400,000 Project coordinator; data manager; data abstractors/interviewers

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Interested Countries

- Rwanda
- Kenya
- Ethiopia
- Vietnam
- S Africa
- Namibia
- Cote d’Ivoire (?)

Adapting LSTEP to Rwanda

Desired characteristics

- National-level
- Representative sample of ART sites
- Random sample of ART patients per site
- Based on minimum data set
- Retrospective cohort analysis
- Non-research determination
- Use existing data system

Protocol Objectives

- Determine proportion of patients alive on ART 6 and 12 months after ART initiation (retention rate)
- Determine the range, standard deviation, and median increase in CD4+ cell count from baseline at 6 and 12 months?
- Determine proportion of patients who have undetectable viral load (≤400 copies/mL) at 6 and 12 months?

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Adapting LSTEP to Kenya

Desired Characteristics

- Phased approach
- National-level
- Representative sample(s)
- Programmatic, immunologic and/or virologic outcomes
- Possible use of DBS v. plasma for VL
- Research determination, with exemption based on minimal risk to human subjects

Challenges

- Large population and geographic area
- Lack of routine laboratory testing
- Lack of standardized ART M & E system
- Extreme heterogeneity of ART sites (“site effect”)
- Retrospective AND prospective surveys desired